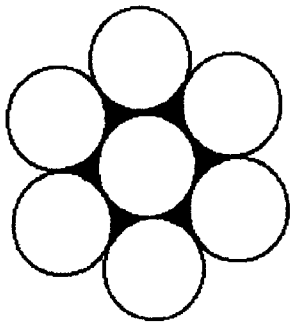
EX PARTE OR LATE FILED

ORIGINAL

DOCKET FILE COPY ORIGINAL

DOCKET FILE COPY ORIGINAL



INTERSTITIAL, INC.
Electromagnetic Effects Consulting

1937 Fenton Lane
Park Ridge, IL 60068

Jack E. Bridges
Ph./Fax (708) 823-4854

RECEIVED
NOV 12 1993
FCC - MAIL ROOM

November 10, 1993

93-142

Office of the Secretary
Federal Communications Commission
1919 M Street NW
Washington, DC 20554

Dear Sir:

Please find my comments in response the FCC's notice of Proposed Rule Making on the matter of "Guidelines for Evaluating the Environmental Effects Radio Frequency Radiation," ET Docket No. 93-142. My specific comments are directed to the IEEE C95.1-1991 standard entitled, "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz."

I have enclosed five sets of comments for consideration by the FCC and other parties. Should anyone have any questions or comments on my material, they are free to contact me at the above indicated address.

Sincerely,

Jack E. Bridges

No. of Copies rec'd 0+4
List A B C D E

COMMENTS ON THE C95.1-1991 SAFETY ASPECTS FOR SHORT DURATION PULSES AND FOR UNGROUNDED METAL OBJECTS IN UNCONTROLLED AREAS

Submitted to the Office of the Secretary
Federal Communications Commission
1919 M Street, N. W.
Washington D. C. 20554

November 10, 1993

prepared by

JACK E. BRIDGES
INTERSTITIAL INC.,
[Electromagnetics Effects Consulting]
1937 Fenton Lane
Park Ridge, IL 60068
Ph. 708-823-4854

C95.1-1991 Safety Aspects for Short Duration Pulses and Ungrounded Metal Objects in Uncontrolled Areas

Summary

The new C95.1-1991 standard, while including major improvements, does not adequately consider the impact on human safety introduced by metal objects in the uncontrolled areas. The standard seems to allow, on the basis of inadequate data, spark induced startle reactions in the uncontrolled areas that could lead to falls. Such is contrary to the approach embodied in ANSI C101.1, which is designed to prevent startle reactions in the home and workplace.

Another problem is that the non-expert is likely to construe that the field intensities permitted in Table 2, Part A are "safe" for grasping the usually encountered metal objects, such as cars or trucks that can be expected in uncontrolled areas. However, such vehicles that are exposed to Part A field intensities can cause unsafe currents to flow in humans as defined by Part B criteria.

Another difficulty is the use of very-high-level, short duration, pulsed, electromagnetic fields or body currents, such as permitted in the new standard. As the duty cycle or pulse width is decreased, the peak electric field intensities or body currents increase to a point where abnormally large potentials will be developed across the human body. These potentials are so large, in excess of 100,000 volts for very short pulses, that non-thermal 60 Hz effects observed in humans should be considered a possibility for higher frequency situations.

The standard did not consider the impact of pulsed fields on medical devices. Based on data developed some time ago, patients with implanted cardiac pacemakers might also be adversely affected by the high intensity, short duration, pulsed electric fields or body currents. At LF or MF frequencies, the pulsed induced body current might falsely inhibit the pacemaker, thereby causing the patient to faint. At higher frequencies, other possible effects might occur, such as functional damage or reduced long-term reliability.

Any concern with short duration pulse effects is not academic. Equipment capable of generating high-intensity short duration pulses has been in use some time for nuclear weapons effects tests. Very-short-pulse radiating equipment is also being tested by the military to burn-out or disrupt enemy electronic gear.

While this new standard provides useful safety criteria for controlled areas, it cannot be easily applied to uncontrolled areas. The possible presence of any arbitrary metal object in the uncontrolled areas makes it difficult, even for an expert, to determine safe field intensities and operating conditions. Further, the standard does not adequately address startle reactions or the effects of very short duration pulses.

To remedy the problems I have identified or to correct any misinterpretations would require additional time and research. Rather than reject the entire standard, it could be issued as a "Recommended Safe Practices" for a trial period This could be accompanied by key papers or comments [such as submitted at this time to the FCC.] The "Safe Practices" could be supplemented by examples. This would provide time to better define the uncontrolled area and to conduct whatever key research is needed.

1.0 INTRODUCTION

This document provides comments on the FCC proposal to adopt as an environmental safety guideline the ANSI/IEEE C95.1-1991 standard entitled, *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz.* Before providing specific comments, it should be noted that the IEEE C95.1 committee has significantly improved the old standard in many respects. One problem is that the radio frequency spectrum is either used by or impinges upon many diverse groups. This has created a major difficulty for the committee to adequately address all conceivable situations. One such difficulty is the use of high-level, short-duration, pulsed electromagnetic fields. Such waveforms could cause non-thermal effects not considered in the development of the C95.1-1991 IEEE Standard.

It is recognized that high-intensity, pulsed electromagnetic fields with spectral content above 3 kHz can induce body currents in humans. But it is not fully appreciated that such pulsed fields, in the order of 10,000 to 100,000 volts/meter, can induce very large, in the order of 10s to 100s of amperes, body currents in the human body. Such currents are usually regarded as innocuous if the pulse duration or duty cycle is sufficiently small that the thermal heating effects remain below the levels specified in the C95.1 standard. However, because of the magnitude of the induced currents, certain non-thermal effects can not be ruled out. Two non thermal effects are considered here, effects on implanted cardiac pacemakers and electroporation effects.

The remaining sections of this document consider first the maximum induced or contact currents that are allowed by the C95.1 standard for pulse conditions. This will be followed by sections that summarize the sensitivity of implanted cardiac pacemakers and electroporation thresholds to the amplitude and duration of the current pulse within the human body. The amplitude and duration's of the different currents will then be compared and recommendations made. Additional comments are provided on the difficulty of defining an uncontrolled environment in the light of the preceding findings. Three Appendices are provided, Appendices A and B summarize the results of some early studies on the sensitivity of implanted pacemakers to 60Hz electric fields. Appendix C presents a discussion on electromagnetic transients in regard to electroporation effects.

2.0 Estimated Induced and Contact Body Currents

For illustrative purposes, the maximum allowable [per C95.1 criteria] induced or contact body currents through both legs are calculated for pulsed wave forms that have principal frequencies ranging from 0.003 to 10.0 MHz for uncontrolled environments. One pulse per second was assumed and the pulse width was assumed to be equal to one-half the duration of a complete cycle of the principal frequency. The contact current was developed for body current pulses that had principal spectral content around frequencies

that ranged from 0.003 to 10.0 MHz. The induced body currents from electric fields were calculated as limited by the 100,000 volts per meter requirement also for the same pulse conditions and frequency range.

Most of the exposure limits in C95.1-1991 are based on thermal Joule heating effects. However perception thresholds are also considered. Based on the same rate of heating for a pulse type current, the Joule heating effect of averaged current, I_{avg}, for a rectangular peak pulse of I_p amperes and an inter pulse current of 0 amperes is defined as follows:

$$(I_{avg.})^2R(t_2 - t_0) = (I_p)^2(R)(t_1 - t_0) \quad (1)$$

where, $t_2 - t_0$ is the time between pulses, and
$t_1 - t_0$ is the duration, t_p, of the rectangular square-topped pulse,
R is any resistance, such as the resistance of the human body.

To simplify, we can define the duty factor, d, as $(t_1 - t_0)/(t_2 - t_0)$.

The relationship between the peak and average current based on equivalent Joule heating becomes:

$$I_p = I_{avg}(d)^{-1/2}. \quad (2)$$

Since the C95.1 safety limits are specified in term of the frequency, the pulse width is approximated to be equal to one-half the period of the frequency noted in the C95.1 standard. This centers the frequency spectral content around the single-valued frequencies noted in C95.1.

The induced body current in controlled environments can be estimated from a relationship that views the standing human as an electrically short monopole as developed as developed in the transmission line reference book (anon. 1975)

$$I_b = [jw\ e_oE][(h)(C_{og}/e_o)] \quad (3)$$

where, I_b is the body current through both legs,
w is the angular frequency,
e_o is the permittivity of free space,
E is the electric field strength,
h is the effective height of the human and
C_{og} is the capacitance of the human to ground.

The terms in the first bracket represent the displacement current per unit area, and the terms within the second bracket the equivalent area. Based on the above, the following empirical relationship was developed by Deno (1977).

$$I_b = (5.4)(h^2)(E)(f/60)(10^{-9}) \quad (4)$$

where, I_b is the body current through both legs in amperes,
h is the height of the human subject in meters,
E is the electric field strength in V/m and
f is the frequency in Hz

Table 1 provides a summary of the different body currents that arise from contacts with metal objects or that are induced by the electric field as a function of frequency [column I]. Column II presents the maximum average allowable current as defined by Table 2, Part B of C95.1-1991. Column III notes the duration of a pulse equal to one-half the period of the principal frequency as noted in Column I. Column IV presents the maximum allowable pulse current from contact with metal objects based on the data in Columns II and III, a pulse repetition rate of one pulse per second and on equations (1) and (2) and note (c) of Section 4.1.2. Column V presents the peak current based on the 100,000 volt/meter limit of note (f) of Section 4.1.2. For comparison purposes, the 100,000 volt/meter calculation is also made for frequencies less than 0.1 MHz.

TABLE 1

A Summary of Maximum Allowable Induced or Contact RF Body Currents for Uncontrolled Environments for One Pulse per Second and Pulse Duration's Equal to 1/2 the Period of the Principal Frequency per C95.1-1991 Criteria

I Principal Frequency MHz	II Average Current Amperes	III Pulse Width Micro-Seconds	IV Contact Pulse Body Current Amperes	V Induced Pulse Body Current Amperes
0.003	0.003	167	0.21	0.08
0.01	0.009	50	1.27	0.27
0.03	0.027	17	6.54	0.82
0.1	0.09	5	40.2	2.70
0.3	0.09	1.7	69.0	8.20
1.0	0.090	0.5	127.0	27.0
3.0	0.090	0.17	218.0	82.0
10.0	0.090	0.05	402.0	270.0

3.0 Pacemaker Effects

The very large values of induced body currents shown in Table 1 might adversely affect patients with implanted cardiac pacemakers or with other types of implanted electronic medical devices. Such currents can disrupt the operation of the pacemaker in several ways. For pulsed fields with a low-frequency spectral content, the induced internal body potentials might mimic the potentials created by a normally functioning heart. If this occurs, this could falsely inhibit the operation of an R-wave inhibited pacemaker, thereby causing the patient to faint. For pulsed fields with a high frequency content, similar effects can be induced by the non-linear response of the electronic devices in the pacemaker. At the very high frequencies where the induced current becomes very large, functional damage, although unlikely, might occur. Also high internal body currents might promote necrosis around implanted electrodes.

Appendices' A (Bridges 1978a)and B (Bridges 1978b) summarize some of the early work on how electromagnetic fields interact with implanted pacemakers. The sensitivity of various pacemakers as measured some time ago are summarized in Table 2 as noted in Appendix B.

Table 2

Calculated Body Current Necessary to Revert a R-Wave Implanted Cardiac Pacemaker in Microamperes

	Lead Arrangement		
Pacemaker Sensitivity	Bipolar	Monopolar Pectoral	Monopolar Abdominal
12 mV	6000	1800	1000
1 mV	500	150	88
0.45 mV	230	70	40

4.0 Electroporation Effects

Electroporation is a possible non-thermal body-current induced biological effect. Electrical currents flowing within body tissues develop large potentials across the membranes of

cells. Such large transmembrane potentials, if applied sufficiently long can create large "holes" in the cell membranes. Depending on the circumstances, the "holes" can be

temporary or permanent. Temporary electroporation is used to introduce DNA into cells and permanent electroporation is currently being used to sterilize foods or to treat tumors (Weaver 1993). Recently, it was discovered that permanent electroporation effects in victim of shock from high voltage lines were responsible for the progressive necrosis that often lead to amputation of the upper limbs Gaylor (1989). These victims of shocks from high voltage lines experienced tissue damage far away from any obviously burned tissue. The long skeletal muscle cells were found most likely to experience permanent electroporation.

Table 3.0 from Appendix C (Bridges 1993) summarizes briefly high-level, pulse current electroporation effects in humans. The unknown factor here is not amplitude so much as the duration of the pulse needed to cause either temporary or permanent effects. In the case of in vitro tests, the threshold electric field to cause permanent effects did not vary significantly until the pulse width was reduced below one microsecond (Kinosita, 1977). However, the in vitro results were for spherical blood cells; and, therefore, the in vitro results might not be reliably extended to the human situation. Significant geometric and proximity differences exist between the long muscle cells in humans and the spherical blood cells in the in vitro arrangement.

The pulse duration influence on possible effects is further illustrated by "carpet shocks." Humans, when walking across carpets can become electrostatically charged to several thousand volts or more. Upon contacting an uncharged metal object, a spark discharge occurs that results in a body current pulse in the order of 2 to 10 amperes and exhibits a duration of a few to 10's of nanoseconds. While such pulses of current are often painful and may cause a pinhole burn, the health effects of such shock are regarded as innocuous. This situation further illustrates the sensitivity of any electroporation effect in humans to the duration of the unipolar portion of the current pulse

TABLE 3
Status of Pulsed-Current, Electroporation Effects

Pulse Amplitude	Pulse Duration	Bio-Effect	Health Effect
5 to 20 A	10's of ms	Perm. Elect'poration	Tissue Damage
0.7 to 2.8 A	10's of ms	Temp. Elec'poration	??????????
0.03 to 2.8 A	30 ns to 1 ms	????????	??????????
0.01 to 10 A	1 to 30 ns	?????????	Innocuous??

5.0 Discussion on Non-Thermal Effects of Very-Short, Large Current Pulses

Table 1 notes that the pulsed body current that arises from contact with metal can be as large as four hundred amperes. Assuming a body impedance of 500 ohms, this implies a transient pulse potential in the order of 200,000 volts that is applied to a human contacting an ungrounded large metal object. Such a potential can be developed by touching a crane which is mounted on rubber tires, which has an extended, near-vertical boom and which is exposed to 100,000 volt/meter pulsed wave form. Gandhi (1982) has considered similar safety issues for the more commonly available vehicles.

Based on the data in Appendices A and B, and as summarized in Table 2, the 60 Hz body current to affect implanted cardiac pacemakers ranged from 0.000040 amperes [40 microamperes] for the most sensitive situation to 0.006 amperes [6000 microamperes] for the least sensitive situation. While the body current measurements are based on 60 Hz currents, it was my experience that the sensitivity of the pacemakers measured did not change dramatically with frequency throughout the lower audio band. At higher frequencies above the mid-point of the audio band, the some of the pacemakers apparently employed low-pass filters in order to suppress radio-frequency interference effects. As a result, the body current needed to initiate a false pacemaker response tended to increase with frequency. However, the amplitudes of the induced or contact body currents even at the higher frequencies are orders of magnitude larger the 60 Hz values needed to cause an effect. Such large amplitudes may be sufficient to overcome any RFI suppression by filters or signal processing in some pacemakers.

As summarized in Appendix C, the 60 Hz body current to cause temporary electroporation ranged from 0.7 to 2.8 amperes and to cause permanent tissue damage ranged from 5 to 20 amperes. Little or no data exists as to how the electroporation thresholds change with the duration of the applied pulse. As suggested in Appendix C, the threshold would be expected to increase [require higher amplitudes to cause an effect] as the duration of the current pulse is decreased. Some data exists from in vitro studies that suggests the threshold remains roughly the same for pulse widths greater that one microsecond. Further, assuming that temporary electroporation occurs, no data exists as to any health effect that might occur. However, it has not been widely appreciated that pulsed 100,000 volts/meter field intensities in the HF band are capable of inducing massive body currents in the order of hundreds of amperes. As a consequence, the health effects of any such massive body currents has not be considered in any depth.

These considerations are not academic, since high-level, pulsed, electromagnetic-radiating sources have been in use for some time and advanced systems that employ pulsed fields are being seriously proposed. For example, the military is developing a high-level pulsed electromagnetic radiating system that is designed to disable the enemy's electronic equipment by mechanisms similar to those noted earlier that might affect implanted

pacemakers. Existing sources of pulsed electromagnetic fields are the nuclear weapon-effect simulators. Advanced radars that are capable of rudimentary target discrimination have been proposed that also employ very high level, short-duration electromagnetic radiation.

6.0 Other Considerations

A major problem with the C95.1-1991 Standard is how to define the geometry and size of metal objects that may be grasped or touched by humans in the uncontrolled areas. Such uncontrolled areas could include ship yards and skyscaper construction sites where large cranes and derricks are used. More typically, the uncontrolled region could include trucks, cars, houses with metal gutters or ham-band radio antennas. Such metal objects can be electrified and become a source of carpet-like spark discharges. Such discharges can be extremely painful from large ungrounded metal objects; and, if unexpected, could cause a startle reaction. Because such reactions could cause a person to fall or to spill hot or toxic liquids, Underwriter Laboratories by means of test procedures defined in ANSI C101.1 limit body currents from applicance or tools to below perception levels.

As noted in the C95.1-1991 standards, defining the conditions for spark discharge reaction from metal objects illuminated by radio waves is difficult. However, this difficulty should not be a reason to ignore the possible effects. I have personally experienced such spark discharges from very large vehicles located under power lines that created 7,000 V/m fields. Such discharges are extremely painful. In my opinion, no one should be continuously subjected to such discharges at work or home as might be construed from the criteria in the C95.1-1991 standard.

A human grasping a metal object in a radio-frequency electric field first experiences the spark discharge just discussed. Next, the human experiences the follow currents which also can be large and exceed those values noted in Table 2, Part B. Methods to calculate the values of such follow currents have been widely treated in the literature (Gandhi 1982). Based on these data (Gandhi 1982), the follow currents in a human grasping a truck illuminated by 615 V/m field at 1 MHz [permitted by Table 2, Part A] would be 3.4 amperes. This value of follow current greatly exceeds the 90 mA limit noted in Table 2, Part B. Thus when the presence of typical ungrounded metal objects is considered to exist in the uncontrolled areas, the different parts of the C95.1-1992 standard seem to be inconsistent, unless carefully considered by an expert.

The criteria as presented might be misconstrued to suggest that cranes exposed the field intensities noted in Table 2, Part A to be automatically "safe" for humans to touch. Additional comments in section 6.7 of the standard would help. An additional set of allowable field intensities that are compatible with the presence of large metal objects in the uncontrolled area should be considered.

7.0 References

Anon. (1975). "Electrostatic Effects of Overhead Transmission Lines" Chapter 8, Transmission Line Reference Book--345 kV and Above, Electric Power Research Institute, Palo Alto, CA, 1975, 248-280.

Bridges (1993). "Electromagnetic Transients: Importance, Coupling and Effects" DoE Annual Review of Research on Biological Effects of Electric and Magnetic Fields from the Generation, Delivery and Use of Electricity, Savannah Georgia, W/L Associates, Frederick, MD

Bridges et al. (1978a). "The Effect of 60 Current on Implanted Pacemakers" 1978 International Symposium on Electromagnetic Compatibility, G-EMC/IEEE, Atlanta Georgia, 258-265

Bridges et al. (1978b). Internal Body Potentials and Currents from ELF Fields and Household Appliances" 1978 International Symposium on Electromagnetic Compatibility, G-EMC/IEEE, Atlanta Georgia, 266-272

Deno (1977). "Currents Induced in the Human Body by High Voltage Transmission Line Electric Field Measurement and Calculation of Distributed Dose," *IEEE Transactions on Power Apparatus and Systems*, Vol. PAS-96, No. 5, September/October.

Gandhi et al. (1982). "Radio Frequency Hazards in the VLF and MF Band" Proc of the IEEE. Vol. 70, No. 12. 1462-1465

Gaylor (1989). "Physical Mechanisms for Cellular Injury in Electrical Trauma," Ph. D. Dissertation, MIT, Boston MA, Sept

Kinosita et al. (1977a). "Hemolysis of Human Erythrocytes by a Transient Field." Proc. Natl. Acad. Sci. 74:1923-1927.

Kinsosita et al. 1977b). "Voltage-Induced Pore formation and Hemolysis of Human Erythrocytes." Biochim. Biophy. Acta, 471:227-242.

Weaver (1993). "Tissue Electroporation for Cancer Tumor Therapy: Issues and Prospects." Invited Presentation, Fifteenth Annual Meeting of BEMS, The Bioelectromagnetics Society, Frederick MD.

COMMENTS ON THE C95.1-1991 SAFETY ASPECTS FOR SHORT DURATION PULSES AND FOR UNGROUNDED METAL OBJETS IN UNCONTROLLED AREAS

APPENDIX A

Presented at the 1978 International Symposium on Electromagnetic Compatibility, Atlanta Georgia.

THE EFFECT OF 60 HERTZ ELECTRIC FIELDS AND CURRENTS ON IMPLANTED CARDIAC PACEMAKERS

J. E. Bridges
M. J. Frazier
IIT Research Institute
10 West 35th Street
Chicago, Illinois 60616

R. G. Hauser, M.D.
Section of Cardiology
Rush Presbyterian-St. Luke's Med. Ctr.
1753 W. Congress Parkway
Chicago, Illinois 60612

Summary

To provide quantitative data on the effect of electric fields from power lines and leakage currents from household appliances on patients with implanted pacemakers, a semi-empirical prediction method was developed. Input data to the prediction model included in vitro susceptibility bench tests on pacemakers, in vivo exposure measurements on baboons with implanted pacemakers, and nonhazardous, noninvasive tests on humans. The results show that widespread interference from 60 Hz electric fields or currents does not constitute a problem for the vast majority of pacemaker patients. Several remedial approaches have been identified for the small group of patients where the possibility of interference may occur.

The results of the above are developed in two parts. This paper, Part I, provides basic information on 60 Hertz environments, pacemaker operation, in vitro bench measurements and in vivo studies. It is shown that in vitro measurements on pacemakers are a valid method for assessing performance of implanted units. Pacemaker sensitivity to 60 Hertz interference, arising from either household appliance leakage current or transmission line fields varies widely. The most pickup occurs for a monopolar lead configuration in combination with an abdominal implant for electric field exposures or hand-to-feet body currents. The monopolar pectoral implant-lead combination is the most sensitive to horizontal electric fields or body currents. The bipolar lead in combination with any location of pulse generator exhibits the least pickup.

Introduction

One of the major medical advances in the last decade has been the development and widespread application of the fully implantable cardiac pacemaker. The electrical output from these implanted pacemakers artificially stimulates the heart, thus making it possible for persons with certain diseases of the heart to lead relatively normal lives. Advances in pacemaker design and in clinical research have resulted in a dramatic increase in the application of such devices. Today, approximately 170,000 patients have implanted cardiac pacemakers, and more than 50,000 are being implanted each year.

Like other pieces of electronic equipment, pacemakers have been found to be susceptible to many forms of electrical interference. Although no catastrophic situations resulting from electromagnetic interference have been reported, concern has been expressed that such interference, for example from ELF sources, might have deleterious effects on the operation of implanted cardiac pacemakers. In recognition of this need, IITRI investigated ELF magnetic field effects in a study for the Navy[1], and conducted preliminary work on the electric field interaction for American Electric Power Company[2]. Recently, the Electric Power Research Institute contracted IIT Research Institute (IITRI) to consider in depth the effect of electric fields from overhead transmission lines on implanted cardiac pacemakers[3].

The primary objective of this paper is to report the findings of this EPRI study on how electric fields from above ground power transmission lines might affect implanted cardiac pacemakers in terms of a primate animal model. A companion paper[4] discusses extending these animal results to the human situation.

In this paper a review of the electrical environments and pacemaker functions is included to provide basic information for those not familiar with these two areas. In vitro and in vivo tests are then discussed to obtain a basic understanding of the behavior of implanted pacemakers.

Review of Environments and Resulting Body Currents

Summary of Power Frequency Environments and Related Body Currents

Sixty Hertz body currents which may affect implanted pacemakers can arise from fields associated with EHV transmission lines or the leakage potentials which appear on commonly used household appliances. In addition, magnetic fields associated either with EHV transmission lines or household appliances can cause similar body currents to flow. However, since the electric field or leakage potential currents tend to dominate in most situations, the magnetic field environments and resulting effects are not considered here but are treated in detail elsewhere[1,3].

Electric Fields in the Vicinity of EHV Transmission Lines

In the vicinity of transmission lines, the near or non-radiating electromagnetic fields are dominant; and therefore, the magnetic and electric fields can be considered as separate entities without significant errors. For simplification, only the dominant vertical electric field component in the vicinity of EHV 60 Hz transmission lines will be considered, and further information is available elsewhere[3,5].

To illustrate the general spatial behavior of the vertical electric field from an EHV transmission line, the measured fields under a 60 Hz 765 kV line are presented in Figure 1. In general, higher voltage lines will tend to produce larger ground level vertical field intensities, but the fields always diminish quite rapidly as the distance from the line is increased.

Of particular interest is the induced body current which arises when a human and/or other type of animal is standing in these electric fields. The induced body current is a strong function of the geometry of the animal, and this is the reason for the selection of the primate baboons over other more commonly used animals such as dogs for use in the in vivo studies. In an average size man, who is well grounded and stands in an electric field, the induced body current will be maximum at the feet and minimum near the head. For the 8000 V/m maximum field shown in Figure 1, the average human would experience approximately 132 μA of body current flowing through his feet into the ground. For

CH1304-5/78/0000-0258$00.75 @ 1978 IEEE

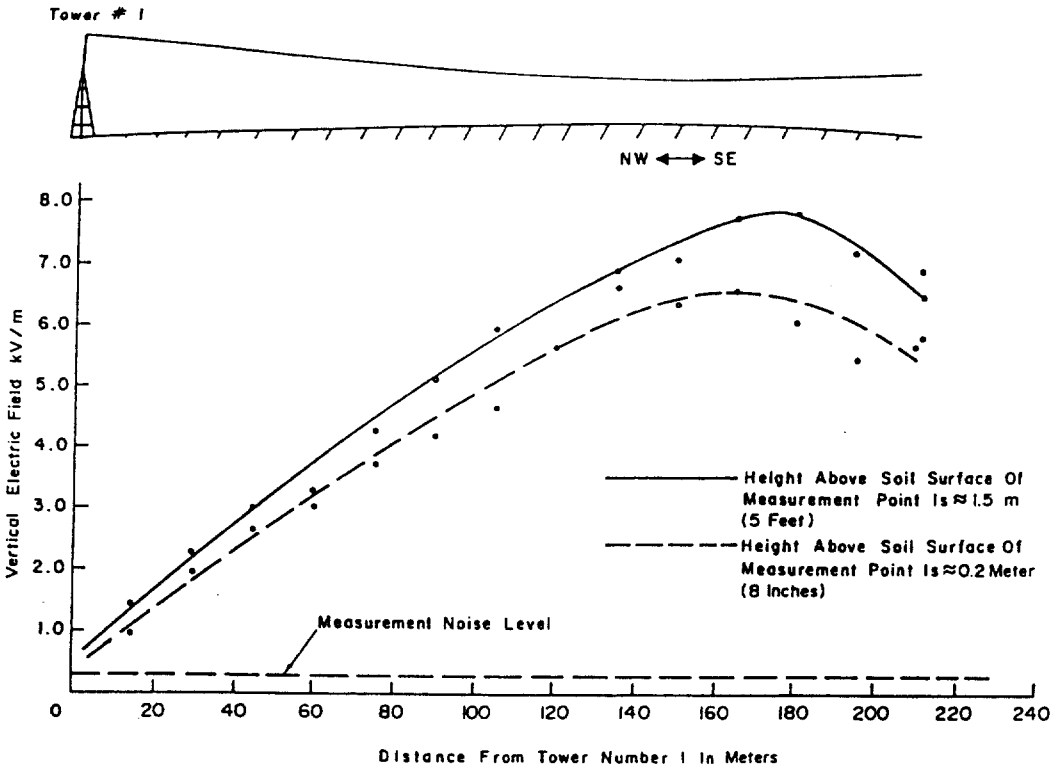


Figure 1 Vertical E Field Under Center Phase of 765 kV Line

comparison purposes, such a current is approximately one-third of the 500 microampere limit which is allowed by Underwriters Laboratory[6] and the American National Standard Institute[7] for a grounded individual contacting a household appliance.

The electric fields which induce current in humans standing beneath power lines can also cause current to flow to ground from metallic objects in the field. If the object is not grounded and connection to ground is established by virtue of a grounded person touching the object, this current will then flow through the person. In general, larger conducting objects, such as a trailer-truck, have more current available than a smaller object to be funnelled to the ground via a person touching the object[8]. In practice, the actual current passing through the individual is governed by a number of complex factors, which include the footwear type as well as other alternate paths for such collected displacement current.

The Household Appliance Environment

Common household appliances produce both electric and magnetic fields in the immediate vicinity of the appliance which seem to be quite small compared to the fields near an EHV transmission line. It must be noted, however, that the actual or effective field is a function of how close the human is to the appliance. For example, the electric field intensity associated with an electric blanket is given as 250 V/m. However, this was measured at a distance of 30 cm from the appliance. If the measurement was made much closer to the electric blanket, even higher field intensities would be noted. Of particular interest is the induced body current which arises when the human is in very close proximity to an electric blanket or an electric heating pad.

To develop some quantitative data in this area, an electric blanket was laid over a person who was reclining on a non-conducting table. The blanket's single-pole switch was connected to the neutral (ground) and this caused the wires within the blanket to be at a 120 volt potential with respect to ground for the open-switch condition. The body current was then measured when the person touched the ground. Under these conditions, 25 μA of body current was noted. However, it is not likely that the human subjects covered with an electric blanket will be touching a grounded object, such as a metallic bed. Tests were also conducted to determine what the worst-case body current would be when a sleeping human was not touching but quite near a grounded metal object. Determination of the thorax current under these conditions proved quite difficult, but on the basis of a series of tests and analyses was inferred to be between 7 and 15 μA[3].

Persons operating or in contact with electrical household appliances and tools can also experience body current. Maximum body current is usually realized where the human is fully grounded (such as standing with leather shoes in soft, moist earth and holding, with a good grip, the metallic shell of the appliance). Both Underwriters Laboratories[6] and the American National Standards Institute[7] require that this body current be less than 500 μA for portable tools and appliances, and less than 750 μA for installed appliances. Prior to the issuance of such standards, many household appliances produced leakage currents in excess of the required values[9].

However, it must be realized that most humans, when in contact with household appliances, are not always well grounded. Typically, such leakage current arises because of the capacity between, for example, motor windings and the ungrounded outer metallic shell. The maximum value of such a capacitance is approximately 0.01 μF for a leakage current not to exceed 500 μA.

To obtain some feel for the leakage current which might flow through a person under typical household conditions, a laboratory simulation was conducted. The ungrounded appliance was simulated by a circuit containing a low impedance voltage source in series with capacitors having a value of either 0.001 or 0.01 μF.

This capacitive source was then connected between a large metal plate on which the person stood and the person's hand. Tests were conducted for several conditions characteristic of different types of footwear. The results are summarized in Table I.

Table I
Body Current Flow For Different Grounding Conditions For 120 Volt Open Circuit Voltage Source

With 0.001 μF capacitor	
Condition	
Grounded	62 μA
3 mm plastic*	14 μA
2.5 cm styrofoam*	5 μA
With 0.01 μF capacitor	
Condition	
Grounded	420 μA
3 mm plastic*	18 μA
2.5 cm styrofoam*	7 μA

*between bare feet and grounded metallic plate

Prolonged exposure to the worst case leakage currents may occur in a variety of household or industrial scenarios--for example, when an operator is using an ungrounded electric floor scrubber or mop, an electrical power tool in a damp basement, or an electric powered hedge trimmer or lawn mower while standing on damp ground. These worst case leakage currents can be significantly reduced if the appliance is third-wire grounded or if double insulation is employed. However, only about 20-25% of the homes in the United States are equipped with an adequate third-wire ground, and only a small fraction of the power tools in use today have double insulation, since this is a recent innovation.

Cardiac Pacemakers--A Review

All cardiac pacemakers function by stimulating the heart by means of electrical impulse applied directly to the heart. The pulses which are emitted from the pacemaker are at a nominal rate of 70 beats per minute, although higher or lower pulsing rates can be obtained from the manufacturer or can be programmed into some pacemakers. At least four types of pacemakers can be identified, the types differing in their sensing and pacing functions in relation to the cardiac electrical output waveform or ECG waveform.

The R-wave (from the ECG waveform) inhibited pacemaker is by far the most common pacemaker employed. This type of pacemaker senses the R-wave portion of the ventricular electrical activity, and emits a stimulating pulse whenever the absence of a detected signal exceeds a predetermined time interval. Whenever an R-wave is present, the pacemaker output is inhibited so that the pacemaker is completely inactive during periods of normal heart activity.

The reason for this design feature is that the majority of pacemaker patients have rate and rhythm disturbances which are intermittent; and hence, they depend on artificial pacemaker stimulation only when the intrinsic heart rate falls below a preset minimum level. Accordingly, the majority of pacemaker patients now receive such non-competitive pulse generators that will artificially pace the heart only when needed, and which will not compete with the patient's own characteristic cardiac rhythm.

In addition, the R-wave inhibited pacemaker incorporates sensing logic to detect the presence of interference which might falsely inhibit the pacemaker. When interference is sensed, the pacemaker reverts to the asychronous or competitive mode In the asynchronous mode, the pacemaker produces pulses at a preset rate.

A pacemaker is also classified with regard to the types of leads employed. Both monopolar and bipolar leads are used, with some pacemakers being convertible from one type to the other. In the monopolar configuration, a single lead carries the stimulating impulse from the pulse generator to the heart. The return path is via body tissue back to the pulse generator which provides a metallic contact with the body tissue and serves as a second electrode.

In the bipolar configuration, two conductors run from the pulse generator to the heart. The two conductors may be physically separated and insulated, or they may run together in a common insulating jacket. In general, bipolar endocardial leads are configured in a common jacket; and the electrodes, which are separated by 15-30 mm, make contact with the endocardium. For bipolar myocardial pacing, two individual insulated leads, which may actually be monopolar leads, are frequently used. The electrodes of the two leads are placed approximately 2.5 cm apart on the ventricular epicardium.

From the standpoint of 60 Hz potentials developed at the pacemaker input due to electric fields or body currents, the significant difference between monopolar and bipolar pacemakers is the distance separation between electrodes. The potential developed across two electrodes, situated in a resistive material through which current is flowing, is proportional to the electrode spacing. Therefore, because of the greater separation, it may be expected that monopolar implants will encounter larger 60 Hz potentials than will bipolar implants.

A variety of implantation techniques are used. When a monopolar lead is used, the implant site of the pulse generator becomes important, since the pulse generator metal case usually serves as the second electrode. It is seen that the abdominal pulse generator configuration shown in Figure 2 exhibits the maximum separation between the heart electrode and the position of the pacemaker for the monopolar configuration.

In the monopolar case, where the pulse generator is implanted in the right or left pectoral region, body currents induced from vertical electric fields or household appliance leakage current flowing from arms to feet, generally result in smaller induced voltages than for the abdominal implant site. On the other hand, current flowing from one arm through the other is likely to produce larger potentials across pectorally implanted monopolar pacemakers than for abdominally located units.

For constant amplitude sinusoidal interfering signals, such as 60 Hz, the only effect of pacemaker operation to be anticipated is reversion to the asynchronous rate. Typically, the transition to the asynchronous mode occurs at some level of interfering 60 Hz potential at the pacemaker input terminals. This is a measurable quantity from the viewpoint of electronics, and hence, is used as a dominant criterion through the remainder of this paper.

The reversion of the pacemaker to the asynchronous mode during periods where interference is present and when the heart is functioning normally, generally results in competition between the spontaneous electrical activities of the normally functioning heart and the electrical stimulus applied by the pacemaker. Some agreement apparently exists that at least brief transitory reversion to this asynchronous mode is acceptable. For example, physicians test implanted pulse generators by applying an external magnet over the unit which deactivates the sensing circuits. The 15-60 seconds of artificially induced competition produced by this technique has not caused any clinical problems for these situations when the patient is resting (non-ambulatory). In the case of longer periods of competition, there seems to be agreement among cardiovascular specialists that there is no serious problem associated with competition due to interference induced reversion to the asynchronous mode.

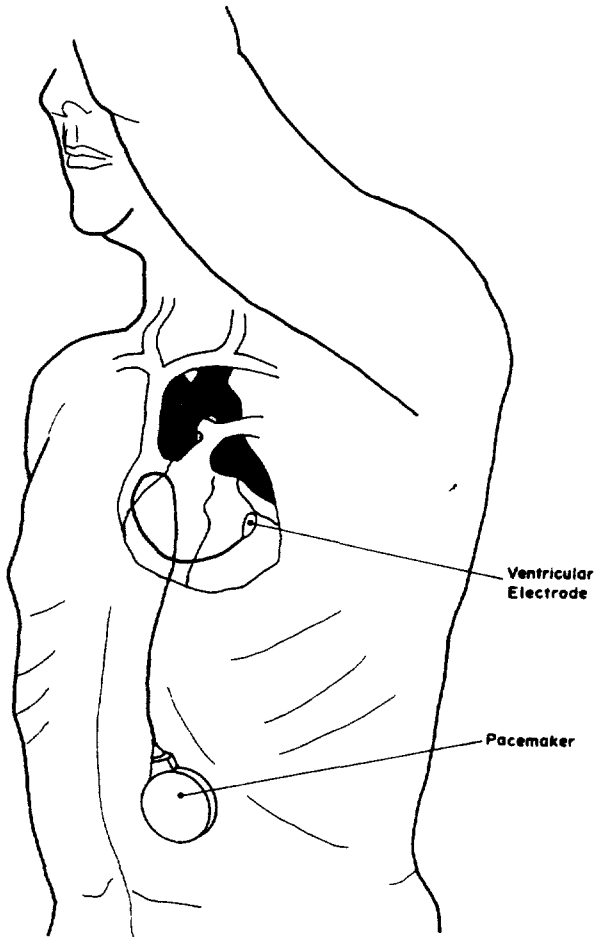


Figure 2 Human Epicardial Implantation

Although no definitive data have been identified, some surveys[10] have indicated that possibly 95% of implants are pacemakers of the inhibited type similar to the R-wave inhibited. Thus, the study of the R-wave inhibited pacemaker units is most appropriate. Further, the same study suggested that approximately 93% of the pacemakers are implanted in the pectoral area, and only 6% are in the abdominal region. Of the 6% that are implanted in the abdominal wall, only about half employ the unipolar lead configuration. Therefore, only approximately 3% of the patients may be implanted with a pacemaker location and lead type combination which will receive the largest potentials due to induced body current.

In Vitro Tests on Pacemakers

Bench tests were conducted on pacemakers for two purposes: 1) to gain a basic understanding of the performance of pacemakers under interference conditions, and 2) to provide the basic data which can be used to predict the performance of pacemakers when implanted in humans. The bench test procedure followed those used in the previous IITRI programs for the Navy[1] and American Electric Power Service Corporation[2]. These bench tests were performed under two conditions--with and without a simulated ECG signal applied to the pacemaker in addition to the 60 Hz interference signal. The case with the ECG signal is representative of the condition when the patient is not dependent on the pacemaker. The second test condition, without the simulated ECG signal applied to the pacemaker, is representative of the case where the patient is completely dependent on the pacemaker output. Figure 3 shows a schematic of the test setup which was employed for the in vitro tests.

The idealized response of demand pacemakers to 60 Hz interference conditions is indicated in Figure 4. Shown in this figure are the generalized output rate responses of a pacemaker as a function of 60 Hz interference voltage level with or without a simultaneously applied ECG input. Figure 4a depicts the situation

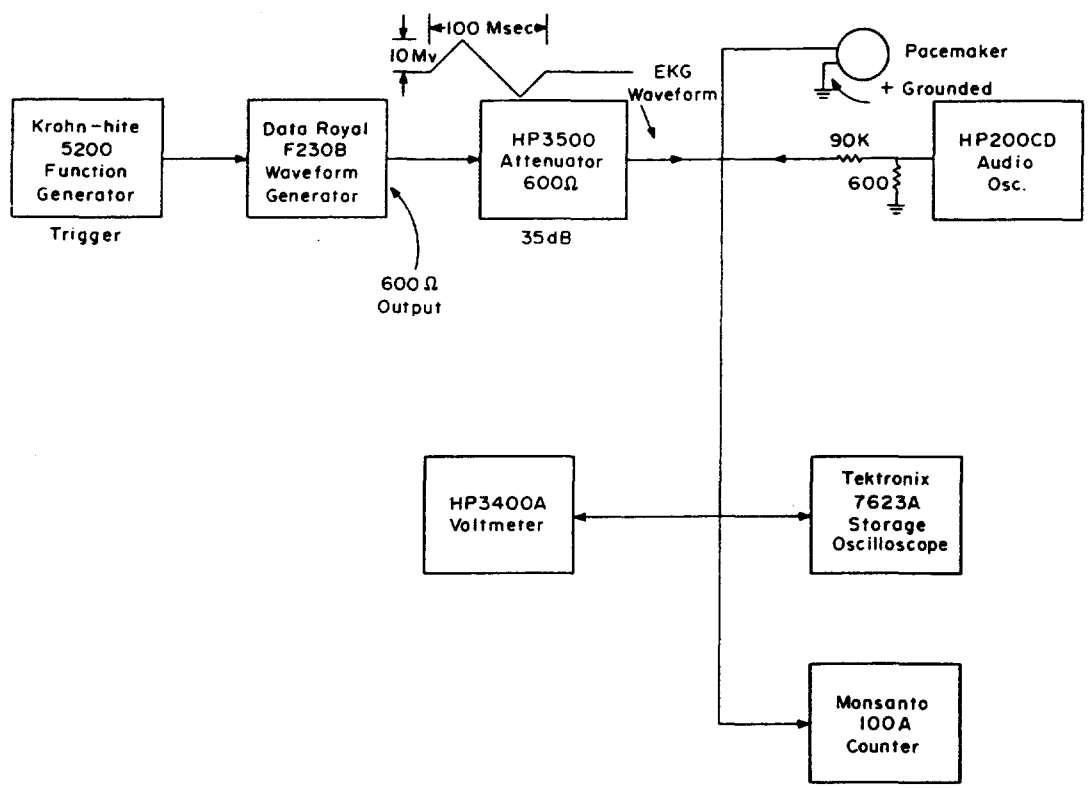


Figure 3 60 Hz Injection Test Set-up

where the heart is functioning normally, and in the case of the in vitro bench tests, a simulated ECG is supplied to the pacemaker. The output pulse of the pacemaker is inhibited by the ECG signal for very low levels of 60 Hz voltage inputs. However, as the 60 Hz voltage at the pacemaker input is increased, a level will be found where the pacemaker recognizes this as an interfering signal and reverts to the asynchronous or interference protection mode. In this mode, output pulses are produced at a rate either established by the manufacturer or preset by electrical or mechanical means. In the case of some pacemakers, a transitional region occurs, indicated by the shaded portion. In this region, it was found that the pulse rate is sometimes irregular or slightly less than the designed asynchronous rate.

The reversion voltage is a quantity determined for each pacemaker tested. The lower the reversion voltage for a given pacemaker, the smaller would be the electric field or the conducted body current level necessary to cause the pacemaker to revert. All other things being equal, it is felt that low reversion levels are an undesirable characteristic of the pacemaker.

Figure 4b shows the results of the simulated case where the patient is totally dependent on the output of the pacemaker. In this case, tests are conducted without the simulated EKG stimulus. For most pacemakers, no significant rate change occurs for any level of 60 Hz input voltage up to a maximum of 50 mV applied to the pacemaker. However, the crosshatch region, shown in Figure 4b, indicates a range of 60 Hz voltage inputs for which the output pulse rate of the pacemaker may be substantially below the design rate. Note that this characteristic is not a desired design function, and was not typically observed.

The 60 Hz direct injection test results were conducted on 13 pacemakers obtained from three manufacturers. These produced the idealized response shown in Figure 4 with reversion threshold ranges from 0.45 mV to 12 mV. The exception was one pacemaker design group from one manufacturer, which produced a false inhibiting characteristic in the range of 0.55 to 1.3 mV, an example of which is shown in Figure 5.

Fig. 4a

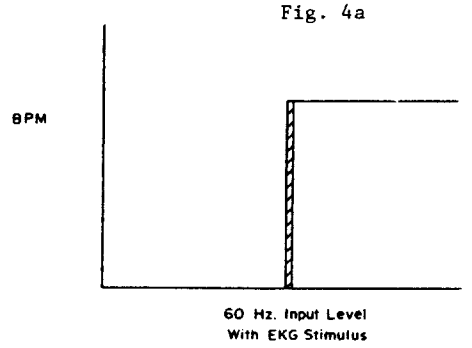


Fig. 4b

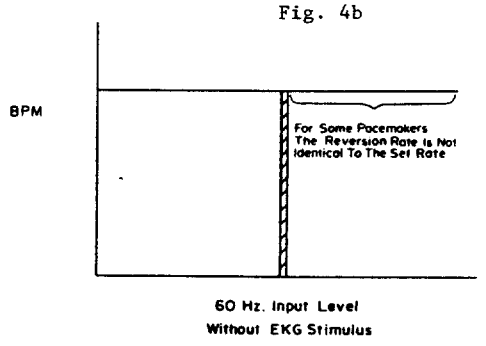


Figure 4 Idealized Response of Demand Pacemaker to 60 Hz Input

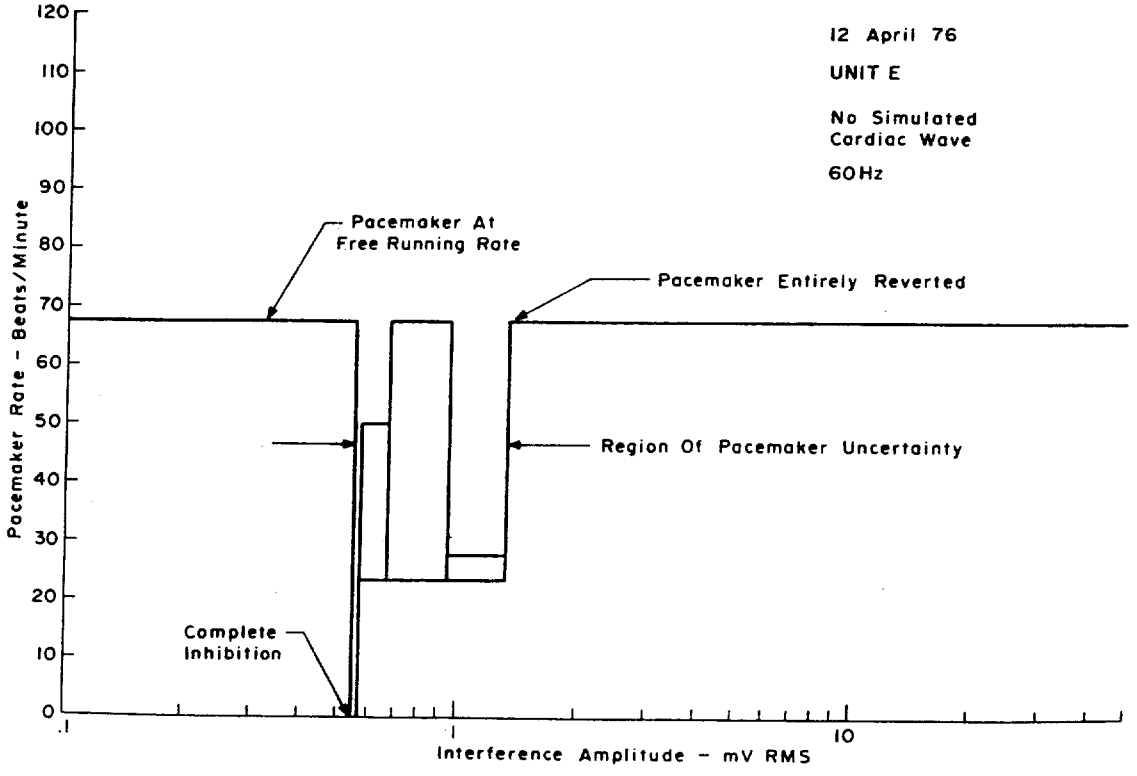


Figure 5 Inhibiting Characteristic of Pacemaker

The false inhibition range for Unit E was observed from 0.55 to 1.3 mV, while the range for the other related design units was considerably less. Above and below these levels of 60 Hz input voltage, the pacemakers operated at their normal design rate. The false-inhibition window shown in Figure 5 would not be considered serious because of the small region of complete inhibition. However, it does seem prudent to include some bench tests similar to those described here to assure that wider windows of total inhibition do not exist. The presence of wide false-inhibition windows could introduce a potential for a hazardous interference situation, although with such wide windows, the circumstances for this to happen would be rare.

The range of input voltages to cause identifiable changes in pacemaker operation, such as reversion, obviously have to be translated to the electric field or body current environments likely to be encountered. This translation from the bench test results to practical electromagnetic environment terms is the topic of the companion paper, which presents the procedures for modeling internal current and potentials.

In Vivo Tests on Baboons with Implanted Pacemakers

In order to investigate the effects of electric fields from power lines on animal test subjects, an electric field facility was constructed at IIT Research Institute within a large, high-ceiling room. The electric field facility consisted of two 14 x 14 foot plates. One plate was laid on the floor and the other was suspended approximately 7 feet above the floor electrode. The plates were driven at 60 Hz from the utility mains by a variable output transformer. By this arrangement, fields to approximately 40 kV/m could be produced. Other equipment was also provided which simulated the effects of contacting household appliances.

Measurements within the facility showed that the field variation over the height of a baboon was less than 10 percent. The field level quoted in test results is the mean value of the field, over a 3.5-foot height above the ground electrode. Measurements showed that the potential across the plates at harmonic frequencies of 60 Hz were all at least 40 dB down from the fundamental. The field in the facility was calibrated by use of the IITRI-developed spherical electric field probe which has been described elsewhere[11].

Special implantable RF telemetry units were also used to monitor the input and output voltages of the implanted pacemakers. By means of the telemetry system, it was possible to ascertain the field or body current thresholds at which reversion occurred and to accurately measure the 60 Hz voltage sensed by the pacemaker.

The use of hard-wired leads to measure the incidence of pacemaker reversion or the 60 Hz voltage at the pacemaker input appeared to be totally inappropriate. During electric field exposures such leads would, in effect, serve as an antenna to collect very large amounts of additional current into the body of the animal. Such large amounts of additional current are obviously undesirable and were avoided by the use of the small implantable telemetry systems.

The small telemetry units were sealed in medical-grade silastic and attached in various ways to the different types of pacemakers. It was also demonstrated that any capacitive displacement current which would pass through the plastic coating would induce little pickup when compared with the pickup experienced by the pacemaker electrodes.

Pacemakers were implanted in the baboon subject animals in an operating suite near the field simulation chamber. These implants were made to simulate as closely as possible the actual surgical procedures and pacemaker locations which might be used in human subjects. Both monopolar and bipolar pulse generators were employed with the pulse generator located in either the pectoral region or abdominal region.

Two classes of tests were conducted. One was to simulate the effect of touching an electrical household appliance or electrified vehicle. The second test exposed the animal subjects to electric fields such as exist near high voltage transmission lines. The purpose of the *in vivo* tests was threefold. First was to demonstrate that the reversion voltage thresholds observed for the *in vitro* tests were the same as that under actual implanted conditions. A second objective was to gain general information on the pickup induced in pacemakers implanted in different locations in the body with different lead and electrode configurations. A third, and perhaps most important objective of the *in vivo* tests, was to provide data which could be extrapolated to the human form by semi-empirical methods.

For two of the six implantations, the reversion thresholds measured *in vitro* were compared with the measured thresholds observed *in vivo* via the calibrated telemetry system. These were considered for both conducted and induced body currents. The results are summarized in Table II, and it is seen that the *in vitro* measurements of the reversion voltage threshold are nearly identical to the actual voltage for reversion. The results of the limb-to-limb body current injection tests are summarized in Table III. The effect of the geometry of the implant configuration can be assessed by normalizing the body current to a unit voltage across the implanted pacemaker electrodes. When this is done, it is seen that the abdominal monopolar implants are, by far, the most effective in converting body current into applied voltage to the pacemaker. It is further seen that for these implants, the most effective limb-to-limb current flow condition is through either arm to the feet. In the case of pectoral implants, the maximum effect is achieved for the arm-to-arm body current flow path. Because of the very small distance between electrodes, the bipolar configuration is the least sensitive to body current flow.

Table II
Comparison of *In Vitro* and *In Vivo* Voltage Reversion Thresholds

Implant	Bench-Test Measured Reversion Threshold	*In Vivo* Meas. Thresholds for Conducted Body Currents	*In Vivo* Meas. Thresholds for Electric Field Induced Body Currents
2	0.45 mV	0.46 mV	0.46 mV
3	0.85 mV	0.7 mV	0.85 mV

Review of the data in Table III shows that implanted pacemaker reversion can occur at body current levels well below the 500 microampere level of permissible household appliance leakage current. It should be noted, however, that these very low body current thresholds, in the order of tens of microamperes, apply only to the baboon test subject. These results are probably indicative of human responses only for the case of pacemakers implanted in very small children. Additional extrapolation of the results to determine predicted body current reversion thresholds for adults is considered in the companion paper.

The effects of direct exposure to uniform electric fields was considered by placing the baboon with an implanted pacemaker in the electric field simulation facility. All baboons were tranquilized during the electrical tests with intramuscular injections of Sernylan. Initial doses of 1 mg/kg were given followed by 0.5 mg/kg doses as needed at 1-2 hour intervals. Intramuscular injections of Atropine suphate, 0.5 mg, were given to reduce salivation.

Figure 6 shows the general configuration used for testing animals with implanted pacemakers within the

Table III
Summary of Reversion Data for Directly Injected Current

Implant No.	Pacemaker Reversion Threshold	Pacemaker Type	Pacemaker Location	Lead Type	Excitation Condition	Body Reversion Current
1	0.45 mV	Monopolar	Right Abdomen	Endocardial Monopolar	Left Arm-Right Foot	10.7 μA
					Head-Right Foot	11.6 μA
					Arm-Arm	224.0 μA
2	0.45 mV	Monopolar	Left Abdomen	Endocardial Monopolar	Right Arm-Feet	11.6 μA
					Head-Feet	11.5 μA
					Arm-Arm	470.0 μA
3	0.85 mV	Monopolar	Left	Epicardial	Right Arm-Feet	27.0 μA
			Abdomen	Monopolar	Head-Feet	26.0 μA
5	0.83 mV	Bipolar	Abdomen	Myocardial Bipolar	Right Arm-Left Foot	1.5 mA
					Head-Feet	1.8 mA
					Arm-Arm	1.25 mA
6	1.2 mV	Monopolar	Right Pectoral	Epicardial Monopolar	Right Arm-Feet	282.0 μA
					Left Arm-Feet	360.0 μA
					Head-Feet	950.0 μA
					Arm-Arm	190.0 μA

electric field facility. The anesthetized animal was tied securely to a plexiglass support structure, so that tests could be performed with the animal standing vertically in the field, while under sedation. The short circuit current-to-ground was measured across a 1000 ohm resistor which was connected to the animal's feet by subcutaneous needles. The implanted RF telemetry unit transmitted external to the body, the signal sensed at the pulse generator terminals. The sensed signal was FM modulated onto an RF carrier at approximately 86 MHz, by the telemetry unit. The radiated RF signal was picked up and detected by a nearby FM receiver. The receiver output was recorded on both magnetic and paper tape. Prior to implanting, the telemetry unit was calibrated to provide an absolute reference for the sensed signal.

The results of several series of tests are summarized in Table IV, which normalizes the field intensity to a 1 mV reversion threshold input at the pacemaker for baboon subjects. As was expected, the abdominal monopolar implants are far more sensitive to the electric fields than the pectoral implants. Most of the reversion field thresholds for the pectoral implants are generally quite high, and, for the most part, exceed field intensity levels associated with existing EHV transmission lines. In the case of the studies on Implant No. 1 where the animal subject's feet were grounded or ungrounded, we note that the reversion threshold was almost double for the ungrounded footwear condition. This fact was anticipated on theoretical grounds.

The results presented in Table IV apply only for the baboon test subjects employed. However, the results are probably roughly indicative of the field intensity thresholds which might be experienced by very small children comparable in size to the test subject baboons. Extrapolating these results to larger sized humans is considered in more detail in the companion paper.

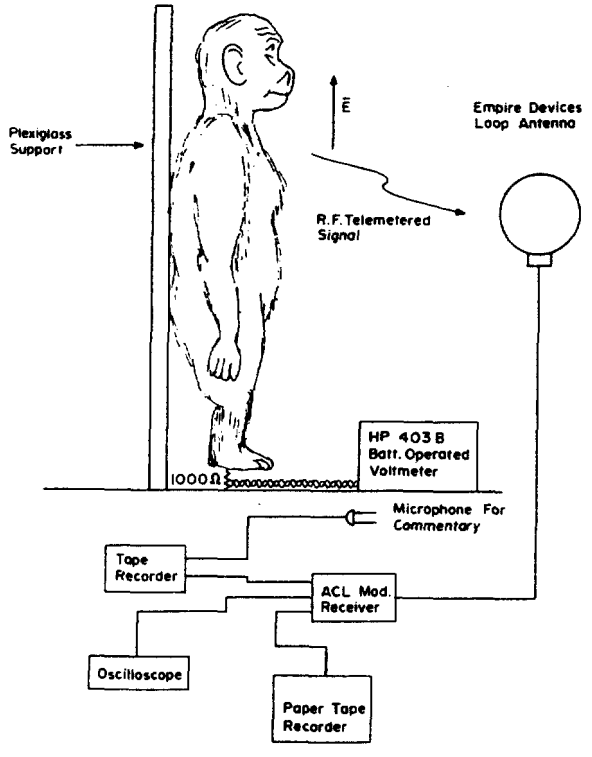


Figure 6 Data Recording Set-up for E Field Tests

Table IV
Summary Of Electric Fields To Develop 1 mV At Pacemaker Input
For Baboon Subjects

Implant No.	Pacemaker Type	Pacemaker Location	Lead Type	Relation To Ground	Position	Electric Field for 1 mV at Pacer Input
1	Monopolar	Right Abdominal	Endocardial Monopolar	Right Foot Grounded	Vertical-Arms to Side	5.33 kV/m
					Vertical-Arms Above Head	3.53 kV/m
				Ungrounded	Vertical-Arms to Side	10.18 kV/m
2	Monopolar	Left Abdominal	Endocardial Monopolar	Both Feet Grounded	Vertical-Arms to Side	4.7 kV/m
3	Monopolar	Left Abdominal	Epicardial Monopolar	Both Feet Grounded	Vertical-Arms to Side	6.1 kV/m
					Vertical-Arms Horizontal	4.59 kV/m
6	Monopolar	Right Pectoral	Epicardial Monopolar	Both Feet Grounded	Vertical-Arms to Side	133 kV/m
				Left Arm Grounded	Horizontal-Right Arm Vertical	34.9 kV/m
					Horizontal Right Arm Vertical Feet Connected to Ungrounded Plate	20.5 kV/m

Acknowledgment

The work described in this paper was sponsored by the Electric Power Research Institute (EPRI) under Contract RP679-1. The EPRI Program Manager was Dr. Harry Kornberg. The authors acknowledge the assistance of numerous co-workers at IITRI, especially R. Zalewski, A. Valentino, S. Tumarkin and W. Lancaster.

References

1. A. R. Valentino, D. A. Miller, and J. E. Bridges, "Susceptibility of Cardiac Pacemakers to 60 Hz Magnetic Fields," IEEE EMC Symposium Record, pp. 10-16, July 1972.

2. R. A. Zalewski, "Effect of EHV Lines on Heart Pacemakers," IIT Research Institute Final Report E8128 (June 1975), sponsored by American Electric Power Service Corporation.

3. J. E. Bridges and M. J. Frazier, "The Effects of 60 Hz Electric and Magnetic Fields on Patients with Implanted Cardiac Pacemakers," IIT Research Institute Final Report E8167 (in press), sponsored by Electric Power Research Institute, Contract RP679-1.

4. M. J. Frazier, J. E. Bridges, and R. G. Hauser, "Internal Body Potentials and Currents from ELF Electric Fields and Household Appliances," a paper to be presented at the 1978 IEEE International Symposium on Electromagnetic Compatibility, Atlanta, Georgia (June 20-22, 1978).

5. J. E. Bridges and V. C. Formanek, "Coupling and Corona Effects Research Plan for EHV Transmission Lines," IIT Research Institute Final Report CONS-2053-1, sponsored by Energy Research and Development Administration, June 1976.

6. Standard for Electrical Heating Appliances, UL 499 (Northbrook, Illinois: Underwriters Laboratories, 1968).

7. ANSI Standard for Leakage Current from Appliances, ANSI Standard, C101.1, November 17, 1970.

8. T. D. Bracken, "Field Measurements and Calculations of Electrostatic Effects of Overhead Transmission Lines," IEEE Transactions on Power Apparatus and Systems, PAS-95(2), (March/April 1976), 494-504.

9. J. Stevenson, "Leakage Currents from Appliances," IEEE Transactions on Industrial Applications, IA-9(1), (January/February 1973), 74-80.

10. V. M. Parsonnet, "Survey of Cardiac Pacing," A Paper Presented at the International Symposium on Cardiac Pacing in Tokyo, Japan, 1976.

11. A. R. Valentino, "A Small Electric Field Probe," IIT Research Institute Technical Memorandum #1 on Project E6212, U.S. Naval Electronic Systems Command Contract N00039-72-C-0106, April 1972.

COMMENTS ON THE C95.1-1991 SAFETY ASPECTS FOR SHORT DURATION PULSES AND FOR UNGROUNDED METAL OBJETS IN UNCONTROLLED AREAS

APPENDIX B

Presented at the 1978 International Symposium on Electromagnetic Compatibility, Atlanta Georgia

INTERNAL BODY POTENTIALS AND CURRENTS FROM ELF ELECTRIC FIELDS AND HOUSEHOLD APPLIANCES

M. J. Frazier
J. E. Bridges
IIT Research Institute
10 West 35th Street
Chicago, Illinois 60616

R. G. Hauser, M.D.
Section of Cardiology
Rush Presbyterian-St. Luke's Med. Ctr.
1753 W. Congress Parkway
Chicago, Illinois 60612

Summary

To provide quantitative data on the effects of electric fields from power lines and leakage currents from household appliances on patients with implanted pacemakers, a semi-empirical prediction method was developed. Input data to the prediction model included *in vitro* susceptibility bench tests on pacemakers, *in vivo* exposure measurements on baboons with implanted pacemakers, and nonhazardous, noninvasive tests on humans. The results show that widespread interference from 60 Hz electric fields or currents does not constitute a problem for the vast majority of pacemaker patients. Several remedial approaches have been identified for the small group of patients where the possibility of interference may occur.

The paper describes the basic modeling concept for relating the fields and body currents to the voltage sensed by the implanted pacemaker. The methods used to obtain empirical data for the model and to verify the model by *in vivo* animal testing are described. The extension of the model to the human form is presented along with examples of predictions for electric field and body current excitation for various implant arrangements and pacemaker sensitivities.

Introduction

One of the major medical advances in the last decade has been the development and widespread application of the fully implantable cardiac pacemaker. Like other pieces of electronic equipment, pacemakers have been found to be susceptible to electrical interference. Although no catastrophic situations resulting from electromagnetic interference have been reported, concern has been expressed that interference, for example, from ELF sources, might have deleterious effects on the operation of implanted pacemakers. The Electric Power Research Institute (EPRI) contracted IIT Research Institute (IITRI) to consider in depth the effects of electric fields from overhead transmission lines on implanted cardiac pacemakers.

The study which is being reported used pacemakers implanted in non-human primates to obtain a basic understanding of how the electric fields affect the implanted pacemakers. The animal tests, which are described in a companion paper, have provided a good understanding of the relative sensitivity of various types of implants to electric fields or conducted body current flow. However, the animal test results do not directly provide quantitative results applicable to the important case of the adult human form.

A semi-empirical model has been developed to provide a quantitative estimate of the level of power line electric field or body current which will cause reversion for pacemakers implanted in adult humans. This paper reviews the basic elements of the model which was developed and the methods used to validate the model by *in vivo* testing with the non-human primates. The model was extended to the human form, by means of non-invasive measurements on human subjects, and is used to provide example predictions of the reversion fields and body current for representative human implant situations.

Implanted Electrode and Body Surface Potential Relationships--Model Development

For a man standing erect in an electric field produced by a transmission line, the current flow through the body is, in essence, parallel to the body axis. Similarly, for important cases of contact with appliance leakage current, the current flow is also basically parallel to the body axis. These cases arise, for example, when an appliance is touched by a hand, and the current flow to ground is through the feet.

The model which has been developed is applicable for the above cases, that is, when the current flow is nominally parallel to the axis of the thorax. Other cases, such as when current flows from hand to hand, have been studied in the animal experiments[1]; however, they have not been modeled due to the inapplicability to the transmission line vertical field case.

General Concepts

In its most basic form, the body is considered as a chain of resistors as is shown in Figure 1. For electric field excitation conditions, the current flow through the body is not a constant, but varies as a function of position along the body. Shown in Figure 1 is a current flow which is non-uniform as a function of position along the body, or the resistor chain. Due to this non-uniform current, different voltages will be developed across the various resistors in the chain, as shown in Figure 1.

From the standpoint of interference to implanted cardiac pacemakers due to power line frequency currents flowing in the body, the important factor is the voltage that is developed across the electrodes of the implanted pacemaker. Since the input impedance of the pacemaker is high relative to tissue impedance, the pacemaker will sense the voltage developed across the intervening tissue between its electrodes. Thus, again referring to Figure 1, if the position of the pacemaker electrodes is known with respect to its position along the resistor chain, the voltage developed across the implanted electrodes is readily determined, once the values of the resistors and the current as a function of position are known.

The above model concept implies that the potential of an arbitrary point within the thorax is only a function of its position along the body axis, for axial thoracic current flow. Thus, the above model implies that the equipotential surfaces within the body are planar and normal to the body axis. Figure 2 shows this condition for a cylindrical representation of a conducting body. Shown are three planes, A, B, and C, which are normal to the current flow I, which is parallel to the axis of the cylinder. Due to the current flow, a potential difference will be developed between the adjacent planes. The potential difference between adjacent planes, separated by an equal spacing, S, will not necessarily be the same, due to resistivity variation, the different cross-sectional areas of the planes, and the non-uniform current flow.

In relating the cylindrical representation of Figure 2 to the chain resistor representation of Figure 1,

CH1304-5/78/0000-0266$00.75 @ 1978 IEEE

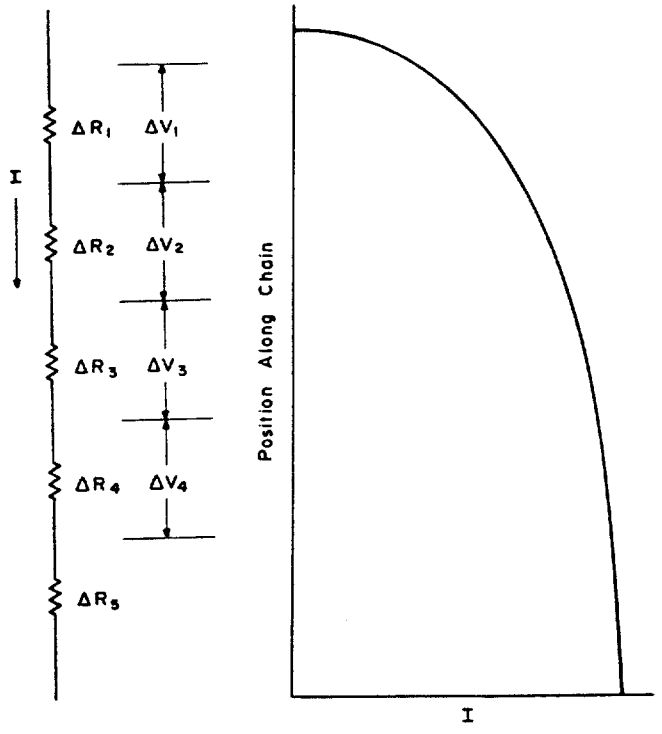


Figure 1 Resistor Chain Representation

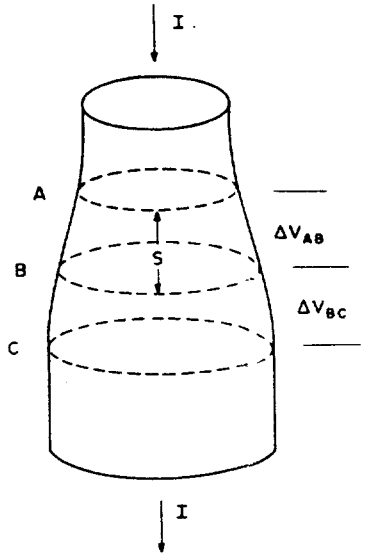


Figure 2 Conducting Cylinder Representation

the resistance values denote the resistance between adjacent planes. The equivalent resistance between adjacent planes can be determined by measuring the potential between adjacent planes and knowing the total current, that is,

$$\Delta R_{ab} = \frac{\Delta V_{ab}}{I} \qquad (1)$$

A key point in the above representation is that the potential difference between the adjacent planes can be measured on the surface of the cylinder. Thus, the necessity for invasive measurements, to determine the potential difference between two points within the cylinder, is eliminated.

In order to use the above modeling concepts to predict the voltage sensed between implanted pacemaker electrodes, it was necessary to verify the planar nature of the equipotential surfaces, and to demonstrate the validity of using body surface measurements to predict internal potentials.

Equipotential Planes for Non-Human Primate

The planar nature of the equipotential surfaces was demonstrated by experiments performed on a baboon test subject. The baboon was chosen as a test subject due to its close physiological relationship to the human. It was felt that if the modeling concepts could be demonstrated using baboon test subjects, extrapolation to the adult human form would only necessitate accounting for the difference in size.

For monopolar pacemaker implants, the metal case of the pulse generator typically serves as the second electrode. Since the pulse generator is generally implanted immediately below the skin, its potential should be quite close to that of the skin at the pulse generator site. However, the heart electrode is located deep within the body and is separated from the surface by the rib cage. Demonstration of the planar nature of equipotential surfaces through the heart, where a pacemaker electrode might normally be placed, was thus felt to be important. Therefore, an experiment was conducted to determine the skin surface points which were equipotential to an electrode located within the heart.

To perform the experiment, a pacemaker pervenous ventricular lead was implanted into a baboon. The lead was advanced into the right ventrical by venipuncture of the right subscapular vein. The lead was routed to the abdominal region through a subcutaneous tunnel, where the connector end of the lead was brought through the skin and exposed. The exposed end of the implanted lead was connected to one side of a voltage sensor; the other side of the voltage sensor was connected to a needle probe used for skin probing measurements. The test arrangement is shown in Figure 3.

By forcing a current to flow from head to foot, as is shown in Figure 3, and by means of the voltage sensor and needle probe, skin surface measurements could be made to determine those points on the surface of the thorax which were equipotential to the catheter tip located in the heart. Other equipotential lines were located by determining skin points that produced a constant potential difference to the implanted catheter tip.

By use of fluoroscopic and x-ray examinations, it was determined that the points on the thorax surface which were equipotential to the catheter tip within the heart, were essentially on a plane normal to the body axis, that also contained the heart catheter tip. Other equipotential lines on the thorax surface were essentially parallel to the catheter tip equipotential line. Thus, this experiment demonstrated the validity of the planar representation of Figure 2 and the use of skin surface potential measurements.

Field-Induced Body Current

In employing the semi-empirical model to predict the electric field which will cause pacemaker reversion, it is necessary to know the current distribution as a function of height on the test subject. Experiments were conducted using a saline solution-filled lucite cylinder in the electric field facility to determine how the current varies as a function of position within a conductive tall-thin object. By using a small RF telemetry transmitter, immersed in the saline solution-filled cylinder, data were obtained on the current

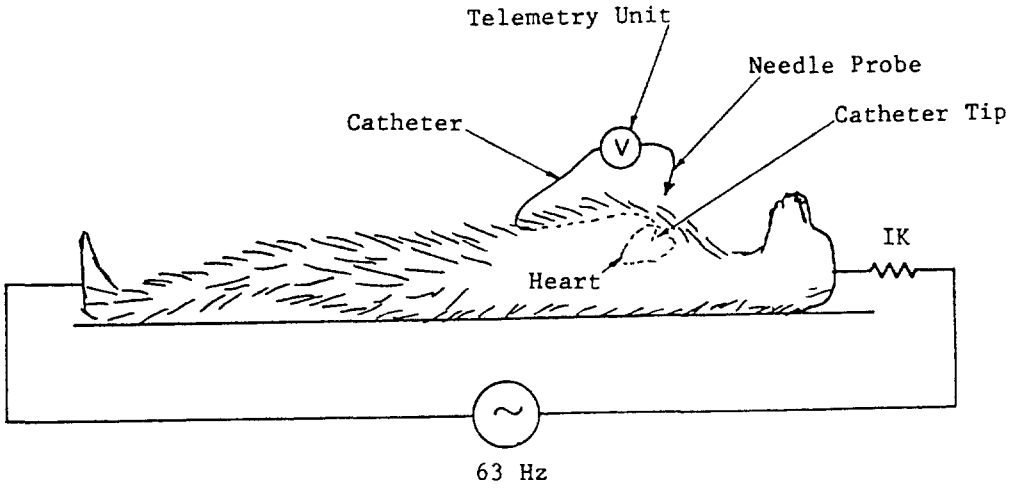


Figure 3 Test Arrangement for Catheter Tip Experiment

distribution as a function of height in the cylinder for electric field excitation. The data obtained, were quite closely approximated over the lower 90 percent of the cylinder, by the expression,

$$I_s(Z) = I_{sc}\left[1 - 0.69\left(\frac{Z}{h}\right)^{2.14}\right] \qquad (2)$$

where

$I_s(Z)$ is the total body current which flows through a cross section at height Z
I_{sc} is the short circuit current to ground from the feet, and
h is the total height.

This expression compares quite favorably to the current distribution from studies with a metalized mannekin[2], for heights below about the shoulders. The above expression for current as a function of body position, was used to predict the potential developed across implanted pacemaker electrodes, for comparison with measurements made in the field simulator. The short circuit current-to-ground, which appears in the above expression, was measured for the baboon test subjects.

Model Verification by Pacemaker Implants in Animals

Further verification of model validity was obtained by experiments using pacemakers implanted into animals. These experiments showed:

- that the potential difference between implanted electrodes can be determined by differential resistance measurements made on the surface of the skin, and knowledge of the current flow;
- that the potential required for pacemaker reversion is the same when implanted as when tested on the bench;
- that pacemaker reversion can be predicted for either electric field or conducted body current excitation conditions.

In Vivo Pacemaker Reversion--Experimental and Prediction

Two of the six pacemaker implants into baboons, which were made on the program, were used for the purpose of validating the modeling procedures. For these two implants, differential resistance data permitted comparison between measured values of electric field and body current required for pacemaker reversion, with values calculated by use of the modeling procedure which has been described. To obtain differential resistance values, a two-needle probe was used to sense the potential drop incrementally along a line on the thorax which was parallel to the body axis. The two needles were separated by four centimeters.

For these measurements, a known current flow was established from head to foot through the animal. Using the known current value and the differential voltages which were measured, differential resistance values were calculated for successive cross-sectional slices, as was depicted in Figure 2. When the implants were made, the projection of the heart catheter tip on the surface of the thorax was determined by fluoroscopic means, thus permitting identification of the catheter tip locations with respect to the equivalent differential resistance chain.

Using the differential resistance approach, the voltage developed across the pacemaker is given by

$$V_{pacer} = \sum_{n} \Delta R(z) \cdot I(z) \qquad (3)$$

In this expression I(z) is the current at the position corresponding to the center of the measured differential resistance $\Delta R(z)$. The summation is over the n differential resistance slices between the two implanted pacemaker electrode locations.

For conducted body current flow, parallel to the thorax axis, I(z) in the above expression is a constant, so that the pacemaker input voltage and the body current are related by the summation of differential resistances between the two implanted electrode positions. Table I shows the results of the conducted body current tests performed with these two implants. Shown are the measured and calculated values of axial thoracic body current necessary for pacemaker reversion. In determining the calculated value of current, the 60 Hz voltage required for pacemaker reversion in the bench tests was the value of voltage used in Equation 3. The bench testing of the pacemakers is described in a companion paper. Also shown in this table is the comparison between pacemaker reversion voltage, as determined by the bench test, and as sensed by the implanted telemetry unit.

Table I
Calculated and Measured Conducted Body Current
for Implanted Pacemaker Reversion in Baboon Test Subjects

Implant	Pacemaker Reversion Threshold		Conducted Axial Thoracic Body Current For Reversion	
	Bench Test	In Vivo*	Measured	Calculated
2	0.45 mV	0.46 mV	11.5 μA	11.7 μA
3	0.85 mV	0.7 mV	26.0 μA	22.7 μA

*Measured by telemetry unit at point of reversion for conducted current test

Table II
Calculated and Measured Vertical Electric Field
for Implanted Pacemaker Reversion in Baboon Test Subjects

Implant	Pacemaker Reversion Threshold		Vertical Electric Field for Reversion	
	Bench Test	In Vivo	Measured	Calculated
2	0.45 mV	0.46 mV	2.12 kV/m	2.13 kV/m
3	0.85 mV	0.85 mV	First Test 5.2 kV/m Second Test 4.3 kV/m	4.50 kV/m

For comparing the calculated and measured electric field necessary to cause reversion for these pacemaker implants, the current as a function of position along the body given in Equation 2 was substituted into Equation 3. The resulting expression relates the voltage across the pacemaker to the short circuit current to ground from the animal induced by the field. For the two animals used in these tests, the short circuit current to ground was measured as a function of the electric field. It was found for animal 2 that the current was 7.3 μA per kV/m, while for animal 3 the current was 7 μA per kV/m.

Using these current values and the measured differential resistance values, the electric field necessary to cause a voltage at the pacemaker input equal to that determined from the bench tests, was calculated. Table II shows a comparison of the measured and calculated values of electric field necessary to cause pacemaker reversion for these two implant conditions. It is seen that the measured and calculated electric fields for reversion are quite close. Also shown in the table is the voltage indicated by the telemetry unit at the onset of field-induced reversion, as compared to the values obtained for the bench tests with these pacemakers.

Field or Current Induced Pacemaker Reversion for Humans

The basic modeling procedures described above for calculating the fields or body current necessary for pacemaker reversion in the experimental animals has been applied to the calculation of pacemaker reversion for implants in humans. The basic procedures and results are described below.

Non-Invasive Human Tests

As in the animal tests, the predictive procedure requires knowledge of the differential thorax resistance over the region of concern for implanted electrodes. The animal tests showed that these resistance values could be obtained non-invasively, by surface measurements.

Using the test setup shown in Figure 4, the differential resistance values were obtained along the thorax for four volunteer human subjects. The data which were obtained agreed quite well with a more extensive series of measurements reported by Gamboa and Adair[3]. From their data on 45 test subjects, they deduced an empirical relationship between the effective thorax resistivity and the cross-sectional area, which is

$$\rho = 240.44 + 0.353A \qquad (4)$$

where ρ is an equivalent uniform thorax resistivity in ohm cm, and A is the cross-sectional area in cm^2.

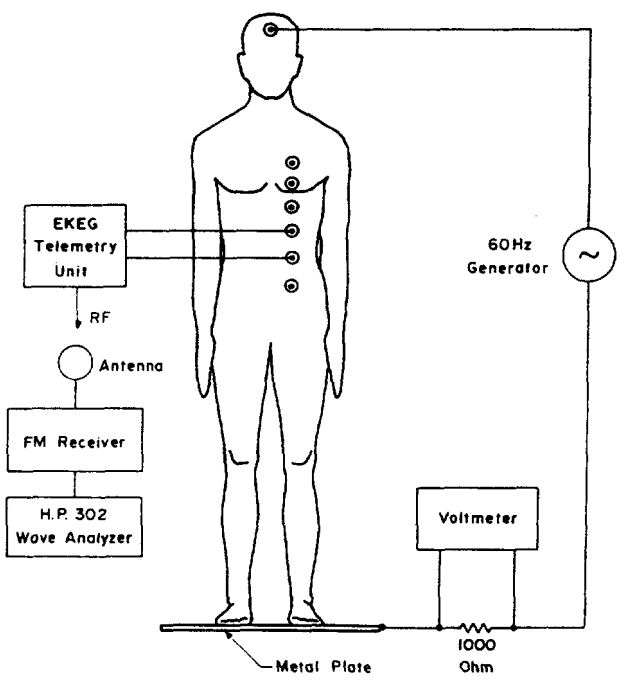


Figure 4 Human Thorax Differential Resistance Test Set-up